REMARKS

Support for the amendments

Claims 41, 54-57, and 69 are canceled without prejudice to their presentation in a continuing or other related application. The claims that depend from them are amended to reflect the cancellation of the base claims.

Claims 29-32, 43, 45, 46, 60-62, and 68 are canceled solely to focus the claim set, for reasons unrelated to patentability, without disclaimer as to the scope of the remaining claims and without prejudice to the presentation of the canceled claims in a continuing or other related application.

The amendments add no new matter to the disclosure.

Request for reconsideration of finality

On 16 February 2007, applicant filed a request under 37 C.F.R. § 1.116 that the examiner withdraw the finality of the outstanding Office action as premature. To date, the Office has not acted on the request. Notwithstanding the present reply, applicant maintains that the action mailed on 29 December 2006 was improperly designated as final. Applicant reiterates its request that the finality of that action be withdrawn.

Priority claim

The Office notes that the amendment of the specification to state a claim for priority in accord with the filing papers and the inventors' original declaration, as submitted in the amendment filed 12 August 2005, was not provided within the period specified in 37 C.F.R. § 1.78(a)(2)(ii). The Office further notes that the amendment was not accompanied by a petition and surcharge as specified in § 1.78(a)(3)(ii)-(iii). The required surcharge and a petition in accord with the requirements of § 1.78(a)(3) are filed concurrently with this reply. Thus, applicant submits that the presentation of the priority claim is proper.

Correction of inventorship

Consistent with facts stated in connection with a petition to correct inventorship that was submitted in parent application serial no. 08/149,099, applicant is filing a request under 37 C.F.R. § 1.48(b) to amend the inventorship in this application. Because no claims to the invention of John E. Leonard remain in this application, the request seeks deletion of his name from the inventorship.

Double patenting

Claims 21, 26, 29-32, 41-43, 45-48, 51-58, 60-62, and 68-72 were rejected on grounds of "obviousness-type" double patenting over claims 1-6 of U.S. Patent No. 5,736,137. Without conceding the merits of the rejection as to any of the claims so rejected in the last Office action, applicant submits a terminal disclaimer over the '137 patent with this reply. Accordingly, the double patenting rejection is moot, and applicant requests that it be withdrawn.

35 U.S.C. § 112, first paragraph

Claims 41, 43, 45-48, 51-57, and 69 were rejected on two separate grounds under the written description requirement § 112, first paragraph.

The Office alleged that the radiopharmaceutical dosages recited in claims 54 and 57 were not described in the specification with reference to the full scope of the claims. Claims 54, 57, and the claims dependent from them have been canceled, and this ground of rejection is therefore moot.

The Office also alleged that there was no basis in the specification for the recitation of "pharmaceutical carrier" in claims 41 and 69. Applicant notes that the specification as filed teaches at page 14, lines 25-29:

> Methods for preparing parenterally administerable [*sic*] agents are described in *Pharmaceutical Carriers & Formulations*, Martin, Remington's Pharmaceutical Sciences, 15th Ed. (Mack Pub. Co., Easton, PA 1975), which is incorporated herein by reference.

The title of the cited publication provides literal support for the questioned language. Nevertheless, to advance prosecution, claims 41, 69, and the claims dependent from them have been canceled.

Because the claims containing the language identified by the Office as the basis for the rejections under § 112 have been canceled, applicant requests that the examiner withdraw the rejections.

35 U.S.C. § 102(b)

Claims 41, 43, 45-48, 51-57, and 69 were rejected under § 102(b) as anticipated by Anderson (US 5,736,137). The theory of the rejection was that because these claims allegedly did not comply with the written description requirement for the reasons stated in the rejection under § 112, first paragraph, they were not entitled to the claimed priority date.

As noted above, the cancellation of claims 41, 47, 54, 57, and the claims that depend from them obviates the rejections under § 112, first paragraph. All of the claims are entitled to benefit under 35 U.S.C. § 120 of, *inter alia*, the application that matured to the '137 patent. Accordingly, the '137 patent is not prior art against any pending claim. As the basis for the theory supporting the rejection under § 102(b) no longer applies, applicant requests that the examiner withdraw the rejection based on the '137 patent.

35 U.S.C. § 102(a)

Claims 21, 26, 41, 42, 58, 59, 69, and 70 were rejected under § 102(a) as anticipated by a 1991 publication by Anderson *et al.* Applicant understands that the citation is to Anderson, D.R., *et al.*, "Immunoreactivity and effector function associated with a chimeric anti-CD20 antibody," abstract of a presentation at the Second IBC International Conference on Antibody Engineering, San Diego, 16-18 December 1991.

Applicant respectfully traverses the rejection. The entirety of the cited reference is reproduced below:

Immunoreactivity and Effector Function Associated with a Chimeric Anti-CD20 Antibody. Darrell R. Anderson, Robert E. McCoobery. Mitchell Reff, Roland Newman, Syamal Raychaudhuri, Nabil Hanna

Murine monoclonal antibody 2B8 (IgG1,K) specifically recognizes the CD20 antigen on the surface of human B lymphocytes. The antibody has the ability to target B cell lymphomas and other malignancies of the B lymphocyte lineage. The V region gene for 2B8 was cloned into a vector with a human G1 K construct and expressed in mammalian cells producing as high as 90 mg/L. Purified chimeric antibody (C2B8) retained the same specificity and affinity when compared to the murine antibody. Effector function studies have demonstrated the added ability of C2B8 to function in human C1q complement dependent lysis and antibody dependent cell cytotoxicity of SB leukemia cells *in vitro*. Comparison of C1q binding by flow cytometry and ELISA confirm both the murine and chimeric antibodies have high affinity, yet only the chimeric antibody could exhibit effector function in human systems. These results suggest that chimeric 2B8 antibody may offer an alternative approach to the treatment of B cell lymphoma in the absence of toxins and radiochemicals.

The Office alleges that this reference "teach[es] the chimeric IgG1 antibody C2B8 (see abstract) wherein the antibody has the variable light and heavy [chain] sequences recited in the claims (see specification) [and] the murine antibody from which the variable regions of C2B8 [were obtained,] 2B8." Applicant notes that the cited Anderson reference has no specification. If the reference is to the present specification, it is of course improper to cite the applicant's disclosure as prior art against the claims.

Applicant also notes that the cited abstract does not teach how to make either the 2B8 or C2B8 antibodies. Before the priority date of the present application, the structure of 2B8 and C2B8 had not been disclosed to the public, and there was no publicly available source of either antibody. The fact that neither the relevant information nor the biological materials in question were public before the filing of the original application to which this application claims priority is demonstrated by a declaration by inventor Darrell Anderson that was filed in the European Patent Office (copy attached). Thus, the mere reference to the laboratory designations of the antibodies does not constitute an enabling disclosure of how to make any product within the scope of the claims in this application. *In re LeGrice*, 301 F.2d 929, 936-939, 133 USPQ 365,

372-374 (C.C.P.A. 1962); *In re Hoeksema*, 399 F.2d 269, 273, 159 USPQ 596, 600 (C.C.P.A. 1968). Because the disclosure of the Anderson abstract fails to place either of the antibodies it names in the possession of the public, it cannot anticipate under § 102. *In re Sasse*, 629 F.2d 675, 681, 207 USPQ 107, 111 (C.C.P.A. 1980).

Additionally, the Anderson abstract does not describe work "by another" within the meaning of § 102(a). Applicant submits with this reply a declaration under 37 C.F.R. § 1.132 by Darrell R. Anderson stating that the work of co-authors Robert E. McCoobery and Syamal Raychaudhuri reported in the abstract was performed under his direction and supervision, and that neither non-inventor co-author made a contribution to the conception of any corresponding inventive subject matter described in the captioned patent application. This showing is sufficient to establish that the experiments described in the abstract represent the work of Dr. Anderson and the other joint inventors named on the abstract. *See In re Katz*, 687 F.2d 450, 454-56, 215 USPQ 14, 17-18 (C.C.P.A. 1982).

In a previous application in the same family as the present application, the examiner took the position that a similar declaration establishing that co-authors McCoobery and Raychaudhuri did not make an inventive contribution was not effective to resolve the availability of the Anderson abstract as prior art under § 102(a) because the authors identified in the publication did not include all of the inventors named in the application. Applicant respectfully submits that such an observation does not constitute a showing that the invention was "known or used by others" within the meaning of § 102(a). First, the standards regarding authorship of a research publication do not correspond to the requirements of the law concerning inventorship. "[A]uthorship of an article by itself does not raise a presumption of inventorship with respect to the subject matter disclosed in the article." *Katz*, 687 F.2d at 455, 215 USPQ at 18. Moreover, the subject matter of the abstract is not coextensive with the scope of the claims pending in the present application. The fact that fewer than all of the named inventors published an abstract relating to less than all of the claimed subject matter does not raise any question concerning the contributions of the other named inventors.

The declaration filed under 37 C.F.R. § 1.63 provides evidence that all of the inventors believe that each made an inventive contribution to at least one claim presented in the

application. This is all the statute requires to properly establish joint inventorship in the application. 35 U.S.C. § 116 provides, in relevant part:

> When an invention is made by two or more persons jointly, they shall apply for patent jointly and each make the required oath, except as otherwise provided in this title. Inventors may apply for a patent jointly even though (1) they did not physically work together or at the same time, (2) each did not make the same type or amount of contribution, or (3) each did not make a contribution to the subject matter of every claim of the patent.

Finally, the Anderson abstract provides no evidence that the invention was known or used by the public. The "known or used" provision of § 102(a) requires knowledge or use by the public. *Carella v. Starlight* Archery, 804 F.2d 135, 139, 231 USPQ 644, 646 (Fed. Cir. 1986); *see also* MPEP § 2132, subsection I. Evidence that fewer than all of the named inventors knew of subject matter relating to some of the claims is not evidence of public knowledge "by others" under § 102(a).

For the reasons discussed above, the Anderson abstract is not prior art to the present claims under § 102(a). Accordingly, applicant requests that the examiner withdraw the rejection.

Conclusion

Applicant believes that the arguments and evidence discussed above provide a complete response to the outstanding Office action and therefore requests that the examiner indicate that all of the pending claims are allowable. Should any issues remain, the examiner is invited to contact Jeffrey Kushan at (202) 736-8914 or the undersigned at (202) 736-8818.

Respectfully submitted,

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